

**Remarks**

The Office Action mailed June 3, 2010 has been received and reviewed. Claims 1-8 are pending, of which claim 8 has been withdrawn from consideration, leaving claims 1-7 as pending and under examination. Claims 1-7 are amended. Applicant respectfully requests reconsideration and withdrawal of the rejections.

**Claim Amendments**

Claims 1-7 are amended to recite peripheral committed stem cells. Support for the amendments may be found in the specification at, for example, page 3, lines 12-15; and page 4, lines 8-10.

**The 35 U.S.C. §103 Rejection**

Claims 1-7 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,488,040 (Jamás) in view of U.S. Patent No. 6,117,850 (Patchen). Claims 1-7 are amended herein. Applicant respectfully traverses the rejection as it may still apply to the claims as amended.

Claims 1, 4, and 5 are independent. Each of the remaining claims depends, directly or indirectly, from one of the independent claims and therefore includes all of the features of the independent claim from which it ultimately depends. Thus, remarks that refer, either specifically or generally, either individually or collectively, to one or more of claims 1, 4, and 5 apply equally to any claim that depends from an identified independent claim. Each of claims 1, 4, and 5 is drawn to a method that involves enhancing activities of peripheral committed stem cells by administering to an individual whole glucan particles (WGP). Claim 1 is drawn to a method of enhancing glucan-mediated committed stem cell proliferation and expansion. Claim 4 is drawn to a method of enhancing tissue repair via committed stem cell recruitment. Claim 5 method of enhancing glucan-mediated committed progenitor stem cell recovery.

In contrast, Jamás discloses using neutral soluble glucan – not whole glucan particles – to enhance hematopoietic stem cell activities to stimulate platelet formation. (Jamás, column 1, line

62 through column 2, line 12, and column 3, lines 27-28). Therefore, Applicant respectfully asserts that Jamas fails to establish a *prima facie* case of obviousness against claims 1, 4, and 5.

The Office Action acknowledges that while “Jamas does not teach the administration of whole glucan particles (WGP) in its method, the soluble  $\beta$ -glucans are made from WGP and according to the teachings in the background of the reference, both the soluble and WGP will increase (proliferate) the number of stem cells.” (Office Action, page 3). Applicant respectfully disagrees with the Examiner’s characterization of Jamas.

Applicant respectfully submits that Jamas does not address WGP’s in any context other than as a starting material for preparing neutral soluble glucan. The Background section of Jamas does not teach that WGP’s can increase proliferation of stem cells. In this respect, Applicant must correct the record. In the previous response, Applicant correctly stated the teaching of Jamas: “Jamas discloses using neutral soluble glucan – not whole glucan particles – to enhance hematopoietic stem cell activities to stimulate platelet formation.” (Applicant’s response, filed November 29, 2010, page 4, emphases in original). However, on page 5, Applicant appears to suggest that Jamas teaches the use of WGP’s to increase numbers of hematopoietic stem cells. This statement was intended to be made with the caveat that even if the Examiner’s construction of Jamas were correct – and Applicant continues to maintain that the Examiner’s construction is incorrect – then the teaching of Jamas still fails to render Applicants’ claims unpatentable.

Applicant therefore reiterates the positions that Jamas fails to provide any guidance regarding the use of WGP’s for increasing proliferation of any stem cell population. As stated in Applicant’s previous response:

Jamas teaches the preparation of neutral soluble glucan from insoluble glucan particles. (Jamas, column 5, lines 27-29). That is, insoluble glucan particles are a starting material from which the neutral soluble glucan is extracted. (Jamas, column 5, lines 50-54, and column 5, line 55 through column 7, line 38). There is no basis, as the Office Action suggests, that the neutral soluble glucan disclosed in Jamas and WGP are interchangeable. Indeed, Jamas expressly teaches that neutral soluble glucan “selectively activate[s] only those components that are responsible for the initial response to infection, without stimulating or priming the immune system to release certain biochemical mediators (e.g., IL-1, TNF, IL-6, IL-8 and GM-CSF)[.]” (Jamas, column 7, lines 59-64). Jamas also teaches that neutral soluble glucan “retains a specific subset of immunological properties

common to  $\beta$ -glucans but uniquely does not induce the production of IL-1 and TNF[.]” (Jamas, column 3, lines 44-48).

(Applicant’s response, filed November 29, 2011, page 5-6, emphases in original).

Jamas therefore expressly teaches that the neutral soluble glucan possesses different biological activities than prior forms of  $\beta$ -glucan, including soluble forms of  $\beta$ -glucan. This teaching is reiterated in Applicant’s specification, which states, “Various forms of particulate and soluble  $\beta$ -glucan have been prepared.” (Applicant’s specification, page 6, line 15). Applicant’s specification then distinguishes between microparticulate  $\beta$ -glucan particles (page 6, lines 15-23), neutral soluble glucan (page 6, lines 23-29), while WGP’s are described as “another form of  $\beta$ -glucan” and described in detail at, for example, from page 6, line 30 through page 7, line 20. The neutral soluble glucan described in Jamas and Patchen are therefore not interchangeable with the WGP’s recited in Applicant’s claims. Moreover, reference in Jamas to “particulate  $\beta$ -glucans” is not interchangeable with the WGP’s recited in Applicant’s claims. Thus, without more specificity, any teaching in Jamas regarding any activity of a “particulate  $\beta$ -glucan” cannot be properly attributed to WGP’s.

In support of this position, Applicant submits herewith the Declaration of William J. Grossman MD/PhD. In Paragraph 3 of the Declaration, Dr. Grossman states:

The structural differences [between neutral soluble glucan and WGP’s] account for the difference in solubility. The structural differences also result in the two forms having different mechanisms of action: they bind to different immunological receptors on different immunological immune cell subsets and, therefore, result in different immunological events. Because these different forms of  $\beta$ -glucan possess different immunological activities, they are not interchangeable for clinical or other purposes. Consequently, the structural differences between the neutral soluble form of  $\beta$ -glucan described in the Jamas patent and the Patchen patent compared to the WGP form of  $\beta$ -glucan recited in claim 1 result in different functional properties that make the combined teachings of the Jamas patent and the Patchen patent useless for predicting the effect of administering WGP’s.

(emphases added).

The Office Action dismisses this point, stating without technical support, “...although not a whole glucan particle is being used, the active portion from the whole glucan particle is being

used and for the same purpose of enhancing stem cells, as claimed.” (Office Action, pages 5-6). Applicant respectfully submits that this is an oversimplified view of the structural and functional differences between neutral soluble glucan and WGP. As Dr. Grossman states in his Declaration, it is not, as argued by the Examiner, a case in which “the active portion of the WGP” is merely maintained for the same purpose. If that were true, neutral soluble glucan and WGP would bind to the same receptors, activate the same immune cells, and have the same immunological effects. This is, in effect, what the Examiner argues without any support. In reality, however, neutral soluble glucan and WGP – in the words of Dr. Grossman – “bind to different immunological receptors on different immunological immune cell subsets and, therefore, result in different immunological events.” Thus, the Examiner’s position that WGP represent just another way of doing what is disclosed in Jamas and Patchen is incorrect. In the event the rejection is maintained, Applicant respectfully requests that the Examiner provide sound, detailed technical support for the position that neutral soluble glucan and WGP are interchangeable.

Also, the Examiner states, incorrectly, “Further, the cited reference of Jamas discloses that whole glucan particles are known in the art for treating progenitor stem cells.” (Office Action, page 6). As explained above, Applicant respectfully disagrees. In the event that the Examiner maintains this position, Applicant respectfully requests a specific citation to the location of Jamas that expresses such a teaching.

Patchen fails to provide any disclosure that can be applied to WGP. Patchen therefore fails to cure the deficiencies of Jamas.

Because Jamas the combination of Jamas and Patchen. fails to set forth all of the features recited in claims 1, 4, and 5, Applicant respectfully submits that claims 1-7 are nonobvious over the combination of Jamas and Patchen. Applicant therefore requests that the rejection of claims 1-7 under 35 U.S.C. §103(a) as being unpatentable over the combination of Jamas and Patchen be reconsidered and withdrawn.

**Request for Rejoinder**

Applicant respectfully requests rejoinder of claim 8 under M.P.E.P. §821.04(a) as requiring all the limitations of an allowable claim. Claim 8, like independent claims 1-7 is drawn to a method that involves administering to an individual whole glucan particles to enhance committed stem cell proliferation.

**Amendment and Response**

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**Summary**

Applicant respectfully submits that claims 1-8 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representative at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop RCE, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17<sup>th</sup> day of October, 2010.

By: 

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